

§ 299.5

(3) No USAN or other official or common or usual name has been applied to a medically useful drug. Any official name published under section 508 of the act will be the established name of the drug.

(f) A cumulative list of U.S. adopted names selected and released since June 15, 1961, is published yearly by the U.S. Pharmacopeial Convention, Inc., in *USAN and the USP Dictionary of Drug Names*. Copies may be purchased from the U.S. Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852.

[40 FR 14041, Mar. 27, 1975, as amended at 49 FR 37575, Sept. 25, 1984; 53 FR 5369, Feb. 24, 1988; 55 FR 11577, Mar. 29, 1990; 64 FR 401, Jan. 5, 1999; 69 FR 18803, Apr. 9, 2004]

21 CFR Ch. I (4-1-12 Edition)

§ 299.5 Drugs; compendial name.

(a) The name by which a drug is designated shall be clearly distinguishing and differentiating from any name recognized in an official compendium unless such drug complies in identity with the identity prescribed in an official compendium under such recognized name.

(b) The term *drug defined in an official compendium* means a drug having the identity prescribed for a drug in an official compendium.

(c) A statement that a drug defined in an official compendium differs in strength, quality, or purity from the standard of strength, quality, or purity set forth for such drug in an official compendium shall show all the respects in which such drug so differs, and the extent of each such difference.